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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/052,855	03/31/1998	PATRICIA A. BILLING-MEDEL	6064.US.P1	9597

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EXAMINER
CANELLA, KAREN A

ART UNIT	PAPER NUMBER
1642	39

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/052,855	Applicant(s) Billings-Medel et al
	Examiner Karen Canella	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3 months* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____ .

2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-9, 17-24, 26-29, 31-34, 36, 37, and 44-58* is/are pending in the application.

4a) Of the above, claim(s) *1-9, 17-24, 26-29, 31-34, 36, and 37* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *44-58* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 7, 2002 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

3. Claims 1-9, 17-24, 26-29, 31-34, 36, 37, and 44-58 are pending. Claims 1-9, 17-24, 26-29, 31-34, 36 and 37 remain withdrawn from consideration. Claims 44-58 are under consideration.

Claim Rejections Maintained

4. The rejection of claims 44-58 under 35 U.S.C. 101, because the claimed invention is not supported by either a credible, specific and substantial utility, or a well-established utility is maintained for reasons of record.

5. The rejection of claims 44-58 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is maintained for reasons of record as stated in Paper No.s 30 and 34.

One of skill in the art would recognize that a gene product, i.e. either messenger RNA or protein, which is prevalent and highly specific to a disease (see: Van de Vijer et al, Molecular and Cellular Biology, 1987, Vol. 7, pp. 1987), is extremely useful as a marker for the detection of disease in that tissue. On the other hand, a gene product, i.e. either messenger RNA or protein, which is prevalent and highly specific to one tissue type **could** be useful for the detection of that tissue type in metastatic lesions (see: Rajkumar et al, Mayo Clinic Proceedings, 1998, Vol. 73,

pp. 533-536). However, no data is provided to teach the specificity of the detection of the claimed ESTs in clinical samples as indicative of colon disease or colon metastatic disease. On pg. 63, lines 25-33 it is stated that a CS141 probe were found a 1.4 Kb mRNA in 1 of 6 normal colon samples and in 4 of 6 cancerous colon samples. The specification also states that the Cs141 probe detected a 1.4 Kb RNA in the colon sample but not in any of the other non-colon RNA samples. However, both PCR (figure 4B) and Western Blot (figure 5) provide evidence that prostate tissue expresses CS141 as both mRNA and polypeptide. This does not constitute persuasive evidence that the ESTs corresponding to the consensus sequence of CS141 are colon specific or colon cancer specific. Thus, the specification fails to demonstrate a specific correlation between the detection of the claimed ESTs and the presence of colon cancer or any other disease.

It is well known in the art that metastatic cancer cells have altered patterns of gene expression in comparison with the non-metastatic precursor cancer cell. For instance, metastatic breast cancer cells are negative for E-cadherin expression, while normal breast cells and non-invasive breast cells are positive (Oka et al, Cancer Research, 1993, vol. 53, pp. 1696-1701). Therefore, it cannot be predicted that the claimed polynucleotides would be expressed in metastatic prostate cancer cells. Furthermore, claims 49, 50, 52, 54, 55 and 58 are drawn to polynucleotides encoding an epitope, a polypeptide, or a method for producing a polypeptide and the specification does not provide evidence the claimed polynucleotides are actually translated into a polypeptide marker wherein the level of expression of said polypeptide would be indicative of prostate cancer or other prostate disease. It is well known in the art that metastatic cancer cells have altered patterns of gene expression in comparison with the non-metastatic precursor cancer cell. For instance, metastatic breast cancer cells are negative for E-cadherin expression, while normal breast cells and non-invasive breast cells are positive (Oka et al, Cancer Research, 1993, vol. 53, pp. 1696-1701). Therefore, it cannot be predicted that the claimed polynucleotides would be expressed in metastatic prostate cancer cells. Furthermore, claims 49, 50, 52, 54, 55

and 58 are drawn to polynucleotides encoding an epitope, a polypeptide, or a method for producing a polypeptide and the specification does not provide evidence the claimed polynucleotides are actually translated into a polypeptide marker that would be useful in the detection of prostate cancer or other prostate disease.

The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed nucleic acids.

6. The rejection of claims 44-58 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is maintained for reasons of record. Specifically, since the claimed invention is not supported by a specific, substantial and credible utility, one of skill in the art would not know how to use the claimed invention.

7. Applicant has not provided any arguments to obviate the pending rejections.

Conclusion

8. This is a RCE of applicant's earlier Application No. 09/052,855. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
August 12, 2002

Brenda Brumback
BRENDA BRUMBACK
PRIMARY PATENT EXAMINER